



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/813,781	03/07/97	WEIDANZ	J 46745

HM31/0227

PETER F. CORLESS, ESQ.
DIKE, BROWNSTEIN, ROBERTS & CUSHMAN, LLP
130 WATER STREET
BOSTON MA 02109

EXAMINER

LUBET, M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 02/27/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/813,781

Applicant(s)
Weidanz et al.

Examiner
Lubet

Group Art Unit
1644

☒ Responsive to communication(s) filed on Mar 7, 1997

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 ~~month(s)~~, or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-59 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-59 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1644

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8, 9-12, 18, 19, 20 drawn to fusion protein comprising a bacteriophage coat gene III protein linked to TCR classified in class 424, subclasses 185.1 and 192.1.
 - II. Claims 1-8, 13-17, 18, 19, 20 drawn to fusion protein comprising a bacteriophage coat gene VIII protein linked to TCR classified in class 424, subclasses 185.1 and 192.1.
 - III. Claims 21-22, 29-30, 45-48 drawn to DNA encoding the protein of Group I, and vector comprising said DNA and method of producing fusion protein encoded by the DNA method of isolating the DNA, classified in class 435 subclasses 23.4, 70.1 and 320.1 and class 536 subclass 23.5.
 - IV. Claims 21, 23-28 and 29-30 and 45-48 drawn to DNA encoding the protein of Group II, and method of producing fusion protein encoded by the DNA method of isolating the DNA vector comprising said DNA, classified in class 435, subclass 23.4, 70.1, and 320.1 and class 536 subclass 23.5.
 - V. Claims 31-36 and 38-44 drawn to a phage library displaying a fusion protein wherein fusion protein comprises a bacteriophage coat protein covalently linked to single chain T cell receptor, classified in class 435 subclass 6.
 - VI. Claims 31-37 drawn to phage library displaying a soluble fusion protein comprising a bacteriophage coat protein covalently linked to a single chain TCR and further comprises a transgene expressing an HLA-A2 antigen classified in class 435 subclass 6.
 - VII. Claim 52 drawn to a single chain T cell receptor classified in class 530, subclass 350.

Art Unit: 1644

- VIII. Claims 49-50, drawn to method of expressing a soluble single chain T cell receptor in a host cell comprising a DNA vector encoding the soluble single chain TCR, classified in class 435, subclass 69.4.
 - IX. Claims 51 drawn to a method of increasing the specific binding affinity of a single chain T cell receptor for a ligand, classified in class 436, subclass 536.
 - X. Claim 53, drawn to a method of reducing binding between a T cell receptor and a ligand by administering a single chain TCR classified in class 530, subclass 350.
 - XI. Claim 54, drawn to a method of inducing an immune response by administering a single chain TCR receptor, classified in class 424, subclass 192.1.
 - XII. Claim 55, drawn to a method of inducing an antibody to TCR receptor, classified in class 424, subclass 192.1.
 - XIII. Claim 56, drawn to a method of detecting a molecule capable of binding TCR, classified in class 435, subclass 7.2.
 - XIV. Claim 57, drawn to a molecule which binds TCR receptor, classified in class 530, subclass 350.
 - XV. Claim 58, drawn to a method of detecting a molecule capable of inhibiting binding between a ligand a T cell receptor by determining the ability of the molecule to inhibiting binding ligand to a fusion protein comprising a bacteriophage coat protein linked to TCR classified in class 435, subclass 7.1.
 - XVI. Claim 59, drawn to a molecule which inhibits binding between a ligand and a T cell receptor, classified in class 530, subclass 350.
2. The inventions are distinct, each from the other because of the following reasons:
3. The proteins of Group I and II are patentably distinct chemical species from the nuclei acids of Group III and IV, although related as the nucleic acids encode the proteins. The proteins can be made without recourse to the nucleic acids by the materially distinct process of

Art Unit: 1644

biochemical purification from natural sources, and the nucleic acids have separate utility as probes for screening libraries.

The proteins of Group I, II, VII are patentably distinct chemical species from the molecule of Group XV, although some species of Group XV can bind the protein of Groups I, II or VII. The molecule can cross-react with other proteins. The protein can be made without recourse to the molecule by biochemical purification from natural sources.

The phage library of groups V and VI are patentably distinct one from the other because they comprise DNA encoding distinct chemical species of proteins.

The phage library of Groups V and VI are patentably distinct from the DNA of Groups IV and V, although related as the phage libraries comprise DNA of Groups II or III. The DNA can be made without recourse to the phage library and can be used as a hybridization probe.

The proteins of Group I, II and VII are patentably distinct proteins which have different structural and chemical characteristics.

The method of producing a single chain TCR of Groups VIII is patentably distinct from the methods of producing a fusion protein comprising a bacteriophage protein-TCR fusion protein of Groups III and IV. The methods of Group VII utilize materially different products.

The method of group IX and the phage library of Groups V and VI are patentably distinct. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product(phage library) as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the products (phage library) as claimed can be used in the materially different processes of screening for antibodies that bind to the fusion product.

The methods of Groups VIII, IX, and XIII are patentably distinct one from the other. They use materially different products and steps and have different goals.

Art Unit: 1644

Group VII and XI and XII are related as product and method of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the and the products as claimed can be used in the materially different processes of screening for cytotoxic T cells specific to TCR.

The methods of XI and XII are patentably distinct because the method of reducing binding between a T cell receptor and a ligand by administering a single chain TCR is not dependent upon induction of an antibody response to the TCR since the TCR can inhibit the binding of TCR to ligand by acting as a competitive inhibitor.

The method of Groups XIII and XV are patentably distinct. They utilize different products, IE bacteriophage display library versus soluble fusion protein. The method of Group XV have different goal and steps from the methods of Group XIII since not all molecules which bind to TCR will inhibit the binding of ligand to TCR.

4. Because these inventions are distinct for the reasons given above and the researches required

5. . Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h)

6. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Group 1600 Group 1640 Art Unit 1644. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martha Lubet in Art Unit 1644 whose telephone number is (703) 305-7148. The examiner can normally be reached on Monday through Friday from 8:15 AM to 4:45 PM.

Serial Number: 08/813,781

Page 6

Art Unit: 1644

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 3053973. The FAX number for this group is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Martha T. Lubet

Feb. 19, 1998



THOMAS M. CUNNINGHAM
PRIMARY EXAMINER
GROUP 1800